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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,836	02/27/2004	Frederick L. Jordan	ORYXE.001C2	8242

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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,836	<b>Applicant(s)</b> JORDAN, FREDERICK L.	
	<b>Examiner</b> Konata M. George	<b>Art Unit</b> 1616	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-16,18-21,24,25 and 27-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-42 and 56-67 is/are allowed.
- 6) ☒ Claim(s) 43-47,50 and 52 is/are rejected.
- 7) ☒ Claim(s) 48, 49, 51 and 53-55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1, 2, 4-16, 18-21, 24, 25 and 27-67 are pending in this application.

#### ***Action Summary***

1. Examiner acknowledges the cancellation of claims 3, 17, 22, 23 and 26.

Therefore, any and all objections and/or rejections are hereby withdrawn.

2. The rejection of claims 1, 2, 4-16, 18-21, 24, 25 and 27-35 under 35 U.S.C. 112, first paragraph as falling to comply with written description is hereby withdrawn as applicant has amended the claims to overcome the rejection.

3. The rejection of claims 4, 5, 18, 19, 27 and 28 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn as applicant has amended the claims to overcome the rejection.

4. The provisionally rejected of claims 1, 2, 4-15, 18, 20, 21, 24 and 31-35 under the judicially created doctrine of obviousness-type double patenting over claims 1, 2, 6, 7, 18, 24-32, 49, 55, 56, 65-68 and 70-72 of copending Application No. 10/856,567 is hereby withdrawn as applicants have filed a terminal disclaimer.

5. The rejection of claims 1, 2, 4-15, 18, 20, 21, 24 and 31-35 under the judicially created doctrine of obviousness-type double patenting over claims 1, 4-14, 17-22 and 25-31 of US Patent No. 6,759,056 is hereby withdrawn as applicants have filed a terminal disclaimer.

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6. The rejection of claims 1, 2, 4-15, 18, 20, 21, 24 and 31-35 under the judicially created doctrine of obviousness-type double patenting over claims 1, 9 and 17-23 of US Patent No. 6,946,144 is hereby withdrawn as applicants have filed a terminal disclaimer.

7. The rejection of claims 1, 2, 4-7, 15, 16 and 18-21 under 35 U.S.C. 102(b) as being anticipated by Toppo is hereby withdrawn as applicant has amended the claims to overcome the rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 43-47, 50 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Toppo (US 5,318,960) as evidenced by The Merck Index (12<sup>th</sup> Ed.).

Toppo discloses a system for transdermal delivery of pain relieving substances. The pain relieving composition comprises a pain relieving substance, an oil surfactant, a co-solubilizer and water (col. 2, lines 66-67). The pain relieving substance may be one or more medicaments including NSAIDs (col. 3, lines 33-65), the oil surfactant can include a polyethoxylated castor oil (col. 4, lines 2-3) and the co-solubilizer can be any alcohol except methanol (col. 4, lines 16-18). Column 5, lines 31-46 teach that in addition to the pain relieving drugs other drugs can be added such as neurotransmitters

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especially calcitonin. The Merck Index is being cited to teach the molecular weight of calcitonin as about 4,500.

***Allowable Subject Matter***

9. Claims 48, 49, 51 and 53-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 1-42 and 56-67 are allowed. The prior art does not teach a transdermal system comprising an ethoxylated oil and delivered agent formulated in the absence of alcohol.

***Conclusion***

11. Claims 43-47, 50 and 52 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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